

### REMARKS

The Office Action contains a single rejection of claims 1-8, 10, 11 and 18-21 under 35 U.S.C. § 112, first paragraph. This rejection is traversed.

The Office Action asserts that the specification does not enable the claimed invention and that a deposit of biological material should be made.

However, Applicants respectfully submit the specification provides a detailed experimental protocol for obtaining both the XbaI-HindII as well as the plasmids of the invention from starting materials described in the art well before the priority date of the present application, like prior art plasmid pVHM603.

According to 37 C.F.R. § 1.802, "[b]iological material need not be deposited, *inter alia*, if it...can be made...without undue experimentation." As further stated in the U.S. Manual of Patent Examining Procedure § 2404.02, "[n]o deposit is required...where the required biological materials can be obtained from publicly available material with only routine experimentation and a reliable screening test." Therefore, the deposition is not required in the present circumstances.

The plasmids pIS284 and pIS287 of the invention can be obtained by one of ordinary skill in the art without undue experimentation and in a reproducible way starting from known biological materials, just following the experimental procedure depicted in the specification (see in particular Examples 1 and 2). The is the reason why it is not necessary for the plasmids to be deposited.

Thus, reconsideration and withdrawal of the rejection of claims 1-8, 10, 11, and 18-21 under 35 U.S.C. § 112, first paragraph, are respectfully, are respectfully requested.

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300, making reference to Attorney Docket No. 101615-00009.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Robert K. Carpenter", written over a horizontal line.

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